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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,919

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Paul Bruschi

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Siemens Corporation
Intellectual Property Department
170 Wood Avenue South
Iselin, NJ 08830

EXAMINER

COBANOGLU, DILEK B

ART UNIT

PAPER NUMBER

3626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/716,919	Applicant(s) BRUSCHI ET AL.	
	Examiner DILEK B. COBANOGLU	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,9-14,17-19,21-27,30,31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9-14,17-19,21-27,30,31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/2003, 5/11/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/4/2008 has been entered.

2. Claims 1-3, 6-7, 9-14, 17-19, 21-27, 30-31 and 33-35 remain pending in this application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 6, 10-14, 17-19, 21, 23-27, 30, 33, 34, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No. 2002/0099570), Uchikubo (US Patent Publication 2003/0046562 A1), and further in view of Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266).

A. Claim 1 has been amended now to recite a method for identifying clinical trial candidates (see abstract of Knight), the method comprising:

- i. receiving from a patient clinical data source, patient data including identities of patients (Knight; abstract, paragraphs:0005, 0058);
- ii. encrypting the identities of the patients to create encrypted versions of the patient identities;
- iii. replacing the identities of the patients in the patient data with the encrypted versions of the patient identities;
- iv. forwarding the patient data (Knight; abstract, paragraphs:0005, 0058) with the encrypted versions of the patient identities to a clinical trial candidate identification service; and
- v. receiving from the clinical trial candidate identification service a clinical trial candidate proposal (Knight; abstract, paragraphs:0005, 0058) including an encrypted version of the patient identity corresponding to a proposed clinical trial candidate;
- vi. decrypting the encrypted version of the patient identity corresponding to the proposed clinical trial candidate; and
- vii. forwarding the decrypted identity of the proposed clinical trial candidate to a candidate contact; wherein the clinical data source is a database containing transactions between healthcare providers and payers. Knight teaches “forwarding the identity of the proposed clinical trial candidate to a candidate contact” (Knight; abstract, paragraphs:0005, 0058);

Knight fails to expressly teach the encrypting the identities of the patients to create encrypted versions of the patient identities, replacing the identities of the patients in the patient data with the encrypted versions of the patient identities and decrypting the encrypted version of the patient identity corresponding to the proposed clinical trial candidate. However, this feature is well known in the art, as evidenced by Uchikubo.

In particular, Uchikubo discloses encrypting the identities of the patients to create encrypted versions of the patient identities, replacing the identities of the patients in the patient data with the encrypted versions of the patient identities and decrypting the encrypted version of the patient identity corresponding to the proposed clinical trial candidate (Uchikubo; abstract, paragraphs: 0010, 0038, 0079).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Uchikubo with the motivation of maintaining security and protect patient's personal information (Uchikubo; 0038).

Knight fails to explicitly teach the method wherein the database contains transactions. Saeed et al., however, teaches a method

which has a database containing transactions between health care providers and payers (see column 9, lines 21-29 of Saeed et al.).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight. One of ordinary skill in the art would have been motivated to combine these features in order to conduct audits and information tracking (see column 9, lines 28-29 of Saeed et al.).

B. As per claim 3, Knight discloses the method of claim 1 as described above. Knight further teaches the method wherein the candidate contact is the proposed clinical trial candidate (Knight; paragraph 0070).

C. As per claim 6, Knight discloses the method further comprising the step of extracting patient medical information from the patient data received from a patient clinical data source (Knight; abstract, paragraphs: 0005, 0021, 0058).

D. As per claim 10, Knight teaches the method of claim 1 as described above. Knight further teaches the method further comprising the steps of: receiving from the candidate contact a status of the clinical trial candidate proposal (Knight; paragraph: 0070); and forwarding the status to the clinical trial candidate identification service (Knight; paragraph: 0070).

E. Claim 11 has been amended now to recite the method of claim 10 wherein the status includes the identity of the proposed candidate (Knight; paragraph: 0070) and the method further comprises the step of encrypting the identity of the

proposed candidate before forwarding the status to the clinical trial candidate identification service.

The obviousness of modifying the teaching of Knight to include encrypting the patient identity (as taught by Uchikubo) is as addressed above in the rejection of claim 1 and incorporated herein.

F. As per claim 12, Knight discloses the method of claim 1 as described above. Knight further teaches the method further comprising the steps of: receiving from the clinical trial candidate identification service, descriptive information about a clinical trial of the clinical trial candidate proposal (Knight; paragraph: 0099); and forwarding the information to the candidate contact (Knight; paragraph: 0099).

G. Claim 13 has been amended now to recite a method for identifying clinical trial candidates (see abstract of Knight), the method comprising:

- i. receiving at least one clinical data record (Knight; paragraph: 0058), each said record including clinical data and an encrypted version of a patient identity uniquely identifying the record without revealing an identity of a corresponding patient
- ii. receiving a candidate selection criterion for a clinical trial (Knight; paragraph: 0058);
- iii. searching the at least one clinical data record for a matching clinical data record based on the candidate selection criteria (Knight; paragraph: 0058); and if a matching clinical data record is found, then forwarding a

contact request from the matching clinical data record (Knight; paragraph: 0070) including at least the encrypted version of a patient identity; wherein the at least one clinical data record is received from an entity controlling a database containing transactions between health care providers and payers.

The obviousness of modifying the teaching of Knight to include the encrypted version of a patient identity (as taught by Uchikubo) is as addressed above in the rejection of claim 1 and incorporated herein.

The obviousness of modifying the teaching of Knight to include database contains transactions (as taught by Saeed) is as addressed above in the rejection of claim 1 and incorporated herein.

H. Claim 14 has been amended now to recite the method of claim 13, wherein the contact request is forwarded to a trusted entity having a key for decrypting the encrypted version of a patient identity.

Knight fails to expressly teach a key for decrypting the encrypted version of a patient identity. However, this feature is well known in the art, as evidenced by Uchikubo.

In particular, Uchikubo discloses a key for decrypting the encrypted version of a patient identity (Uchikubo; abstract, paragraphs: 0010, 0038, 0064, 0079).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Uchikubo with the motivation of maintaining security and protect patient's personal information (Uchikubo; 0038).

I. As per claim 17, Knight discloses the method of claim 13, further comprising the step of receiving descriptive information about the clinical trial, and wherein the contact request includes the descriptive information (Knight; paragraph: 0099).

J. As per claim 18, Knight discloses the method of claim 13 wherein the at least one clinical data record is received from a data exchange service (Knight; paragraph: 0008-0009, 0017, 0019, 0049).

K. Claim 19 has been amended now to recite the method of claim 18 wherein the encrypted version of a patient identity corresponding to a matching clinical data record is forwarded to the data exchange service (Knight; paragraph: 0008-0009, 0017, 0019, 0049).

The obviousness of modifying the teaching of Knight to include the encrypted version of a patient identity (as taught by Uchikubo) is as addressed above in the rejection of claim 1 and incorporated herein.

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L. Claim 21 has been amended now to recite the method of claim 13, wherein the encrypted version of a patient identity corresponding to a matching clinical data record is forwarded to an entity controlling a database containing transactions between health care providers and payers.

The obviousness of modifying the teaching of Knight to include the encrypted version of a patient identity (as taught by Uchikubo) is as addressed above in the rejection of claim 1 and incorporated herein.

The obviousness of modifying the teaching of Knight to include database contains transactions (as taught by Saeed) is as addressed above in the rejection of claim 1 and incorporated herein.

M. Claim 23 has been amended now to recite a method for selecting clinical trial candidates (see abstract of Knight), the method comprising the steps of:

- i. periodically receiving clinical data records, each said record including clinical data (Knight; paragraphs 0005, 0058); and an encrypted version of patient identity uniquely identifying the record and requiring a key for revealing an identity of a corresponding patient, the clinical data records containing transactions between health care providers and payers;
- ii. periodically searching the data records to identify records of clinical trial candidates (Knight; paragraph 0058).

The obviousness of modifying the teaching of Knight to include the encrypted version of a patient identity (as taught by Uchikubo) is as addressed above in the rejection of claim 1 and incorporated herein.

The obviousness of modifying the teaching of Knight to include a key for revealing an identity of a corresponding patient (as taught by Uchikubo) is as addressed above in the rejection of claim 14 and incorporated herein.

The obviousness of modifying the teaching of Knight to include database contains transactions (as taught by Saeed) is as addressed above in the rejection of claim 1 and incorporated herein.

N. System claims 24-27, 30 and 33 repeat the subject matter of claims 23, 1, 10, 13, 6, and 9 (respectively) as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Knight, Uchikubo, and Saeed in the above rejection of claims 23, 1, 10, 13, 6, and 9, it is readily apparent that the Knight, Uchikubo, and Saeed references include a system to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claims 23, 1, 10, 13, 6, and 9 and incorporated herein.

O. Newly added claim 34 recites the method of claim 1, wherein the step of encrypting the identities and contact information of the patients to create

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encrypted versions of the patient identities further comprises: performing a one-way hash.

The obviousness of modifying the teaching of Knight to include the encrypted version of a patient identity (as taught by Uchikubo) is as addressed above in the rejection of claim 1 and incorporated herein.

Knight fails to expressly teach performing a one-way hash.

However, this feature is well known in the art, as evidenced by Saeed.

In particular, Saeed discloses performing a one-way hash (or hash algorithms) (Saeed; col. 8, lines 15-37).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Saeed with the motivation of adding security measures to strengthen the system (Saeed; col. 8, lines 15-37).

P. Newly added claim 35 recites the system of claim 24, wherein the data exchange service performs a one-way hash on the identities of the patients to create encrypted versions of the patient identities.

The obviousness of modifying the teaching of Knight to include the encrypted version of a patient identity (as taught by Uchikubo) is as

addressed above in the rejection of claim 1 and incorporated herein.

The obviousness of modifying the teaching of Knight to include one-way hash (or hash algorithm) (as taught by Saeed) is as addressed above in the rejection of claim 34 and incorporated herein.

5. Claim 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No. 2002/0099570), Uchikubo (US Patent Publication 2003/0046562 A1), Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266) and further in view of Thomas et al. (hereinafter Thomas) (US. Patent Publication 2004/0078238).

A. As per claim 2, Knight, the method of claim 1 as described above. Thomas et al. further teaches the method wherein the candidate contact is a health care provider of the candidate (see page 3, paragraph 0017, lines 13-17 of Thomas et al.).

Knight fails to expressly teach the method wherein the candidate contact is a health care provider of the candidate. However, this feature is well known in the art, as evidenced by Thomas.

In particular, Thomas discloses the method wherein the candidate contact is a health care provider of the candidate (Thomas; paragraph: 0017).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Thomas with the motivation of to be able to establish communication between primary care networks and research and development networks without compromising patient confidentiality (Thomas; 0017).

B. As per claim 9, Knight teaches the method of claim 1 as described above. Thomas et al. further teaches the method wherein the clinical data source is a hospital network (Thomas; paragraphs; 0002, 0010). It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Thomas with the motivation of to be able to properly support research and development (Thomas; 0002).

6. Claims 7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No. 2002/0099570), Uchikubo (US Patent Publication 2003/0046562 A1), Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266) and further in view of Thangaraj et al. (hereinafter Thangaraj), (US. Patent Publication No. 2003/0208378).

A. As per claim 7, Knight, Uchikubo and Saeed teach the method of claim 1 as described above.

However, none of the references explicitly teach the method of reformatting the data. Thangaraj, however, does teach the method

comprising the step of reformatting the patient data received from a patient clinical data source (Thangaraj; paragraph 0019).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight, Uchikubo, and Saeed et al. One of ordinary skill in the art would have been motivated to combine these features to allow data to be captured from and provided to a number of different data sources regardless of data format (Thangaraj; paragraph 0019).

B. System claim 31 repeats the subject matter of claim 7 as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Knight, Uchikubo, Saeed, and Thangaraj in the above rejection of claim 7, it is readily apparent that the Knight, Uchikubo, Saeed, and Thangaraj references include a system to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claim 7 and incorporated herein.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No. 2002/0099570), Uchikubo (US Patent Publication 2003/0046562 A1), Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266) and further in view of Smith et al. (hereinafter Smith) (U.S. Patent No. 5,111,395).

A. As per claim 22, Knight teaches the method of claim 13 as described above. However, none of the references explicitly teach the method wherein a contact request is only sent once for each clinical data record. Smith et al.,

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however, does teach a method comprising the steps of: maintaining records of matching data records (see column 2, lines 35-44 of Smith et al.); and wherein the step of forwarding a contact request including a secure patient code is performed only if that code has not already been forwarded (wherein the secure patient code is a contact name and number in the prior art) (see column 2, lines 35-44 of Smith et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight, Thomas et al., and Saeed et al. One of ordinary skill in the art would have been motivated to combine these features in order to eliminate duplicate records (see column 1, line 40 of Smith et al.).

Response to Arguments

8. Applicant's arguments with respect to claims 1, 13, 23 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not used prior art teach Methods for indexing and storing genetic data 20030039362, Personalized display of health information 6032119 A, Automated networked service request and fulfillment system and method 5995939 A.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. B. C./
Examiner, Art Unit 3626

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626